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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/852,922 | 05/10/2001 | Toshihiro Kuroita | 10089/14 | 5846 |
| 26646 | 7590 | 08/02/2004 | EXAMINER | |
| KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004 | | | HUTSON, RICHARD G | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1652 | |

DATE MAILED: 08/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/852,922

Applicant(s)

KUROITA ET AL.

Examiner

Richard G Hutson

Art Unit

1652

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 29 June 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:


Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-12,25-28,30 and 32-38.

Claim(s) withdrawn from consideration: 13 and 31.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____


Richard G Hutson, Ph.D.
Primary Examiner
Art Unit: 1652

Continuation of 2. NOTE: Applicants proposed amendment of claim 4 wherein applicants attempt to limit claim 4 to those modified polymerases comprising the amino acid sequence of SEQ ID NO: 2, with the specified changes introduces a new issue that would require further consideration and search after final rejection..

Continuation of 5. does NOT place the application in condition for allowance because: Applicants comments regarding the "Election by Original Presentation" and the addition of claim 31 are acknowledged. As previously stated, the invention of newly added claim 31 and Group I, currently being prosecuted, are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by a materially different process such as chemical synthesis. It is recognized that claim 31 is drawn to a method of improving amplification... But applicants attention is drawn to the previous reason for restriction which stated EITHER: (1) that the process as claimed can be used to make other and materially different product OR (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)).

As previously stated, in the instant case the product can be made by a materially different process such as chemical synthesis. The product can be made by chemical synthesis, not the process or method.

The previous inclusion of claims 25-28 and 30 in the previous 112 second paragraph rejection was a mistake. The examiner regrets any inconvenience this has caused applicants and their representative.

The rejection of claims 4-12, and 32 under 35 U.S.C. 112, second paragraph, remain in light of the non entry of applicants proposed amendment.

The rejection of claims 1-12, 25-28, 30 and 32-38 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for the reasons previously made of record.

Applicants comments regarding applicants submission that in contrast to the statements made in the rejection that "there is no disclosure of any particular structure to function/activity relationship in the disclosed species" they do disclose such a relationship are acknowledged but found non-persuasive because applicants discussed structure to function relationship is minor and insufficient to describe the breadth of the claimed invention.

As discussed above and previously, the rejection of claims 1-12, 25-28, 30 and 32-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for any modified thermos table DNA polymerase having 3'-5' exonuclease activity, wherein in the DX1EX2X3X4H sequence within the EXO I region of the thermos table DNA polymerase, histidine (H) has been replaced by another amino acid is maintained for the reasons of record and as discussed above, applicants discussion regarding the structure to function relationship is insufficient to enable the broad scope of the genus of modified thermos table polymerases claimed..